ENVIRONMENTAL TESTING LABORATORY CERTIFICATION BULLETIN

Division of Epidemiology and Laboratory Services
Bureau of Laboratory Improvement
Environmental Laboratory Certification Program (ELCP) **Volume 09, Number 02**
June 2003

Matrix Types

The term matrix comes up in a couple different places when discussing laboratory certification.

Field of Accreditation Matrix - When talking about matrix as it relates to certification [matrix, method/technology, analyte], these matrix definitions shall be:

Drinking Water: any aqueous sample that has been designated a potable or potential potable water source.
Non-Potable Water: any aqueous sample excluded from the definition of Drinking Water matrix. Includes surface water, groundwater, effluents, water treatment chemicals, and TCLP or other extracts.
Solid and Chemical Materials: includes soils, sediments, sludges, products and by-products of an industrial process that results in a matrix not previously defined.

To complete the list from the NELAC standards, although not used in the Utah program:

Biological Tissue: any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.
Air and Emissions: whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter, or other device. (NELAC)

Quality System Matrix – When talking about a matrix used for purposes of batch and quality control requirements. A matrix is considered one of the following:

Aqueous: any aqueous sample excluded from the definition of Drinking Water matrix or Saline/Estuarine source. Includes surface water, groundwater, effluents, and TCLP or other extracts.
Drinking Water: any aqueous sample that has been designated a potable or potential potable water source.
Saline/Estuarine: any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.
Non-aqueous Liquid: any organic liquid with <15% settleable solids.
Solids: includes soils, sediments, sludges and other matrices with >15% settleable solids.
Chemical Waste: a product or by-product of an industrial process that results in a matrix not previously defined.
Biological Tissue: any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.
Air and Emissions: whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter, or other device.

For the certification program the differentiation of matrix is done in parallel with the separate regulatory programs. That means certificates for Safe Drinking Water Act testing includes all analytes and methods for Drinking Water matrix, Clean Water Act testing for Non-Potable Water matrix, and Resource Conservation and Recovery Act testing for Solid and Chemical Material matrix.

Internal Audits

NELAC 2001 5.5.3.1 Internal Audits
A slight clarification for the current NELAC standard is found in the 2003 standard at **5.4.13.1** *The laboratory shall periodically, in accordance with a predetermined schedule and procedure, and at least annually, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this Standard. The internal audit program shall address all elements of the quality system, including the environmental testing activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by*

trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Personnel shall not audit their own activities except when it can be demonstrated that an effective audit will be carried out.

The purpose of the internal audit is to evaluate the effectiveness of the laboratory in complying with the laboratory's own quality system as well as the requirements for certification. The internal auditor should evaluate specifics such as the effectiveness of the corrective action procedures if finding and correcting problems, how close an SOP follows the declared method, the completeness of standard tracking logs, the contents of final reports and the accuracy of data packages, etc.

The audit must address **all** elements of the quality system and specifically mentions the testing itself.

What is required for the internal audit as documentation?

The laboratory:

1. needs a written procedure that covers what will be reviewed, by whom and how often;

2. needs a schedule outlining when each part of the complete quality system will be audited [keeping within the one-year minimum];

3. must have corrective action documentation;

3. must have the records of the reviews and reports of findings; and

4. must have reports to management.

How does the State assessor evaluate the internal audit?

The State assessors evaluate your quality system against the requirements of the State rule [R444-14] and industry standards.

They then evaluate your audit procedure against your quality system.

Continuing on, they will evaluate the actual documentation from internal audit against what your audit procedure describes.

The internal audit documentation is evaluated for completeness, timeliness and meeting certain technical requirements such as the independence of the auditor, organization of the audit and the minimum frequency of the audits.

NELAC, NELAP, EPA, ELCP

There are times when we get questions about the relationship of the State laboratory certification program, the National Environmental Laboratory Accreditation Conference [NELAC] standards, the National Environmental Laboratory Accreditation Program [NELAP] and the EPA.

EPA has federal statutory responsibility to "protect human health and to safeguard the natural environment — air, water, and land — upon which life depends". The states are charged to perform the hands on tasks within their boundaries. Part of the requirements of being a primacy state [the state takes the first responsibility for environmental protection] is to create a testing laboratory within the state to perform all environmental testing used for regulatory purposes. There is an option available where the state may create a laboratory certification program to allow for private sector laboratories to perform regulatory testing if they meet requirements acceptable to EPA.

The ELCP is that certification program and EPA reviews the program at least every three years.

The ELCP is required as part of the agreement with EPA to be a primacy state. The ELCP receives its authority to exist and act from state law. Laboratories are certified under state authority and are considered state-certified laboratories.

The administrative law we use to enforce the state law contains requirements that each laboratory must meet to become certified. These requirements now include some standards developed by a national organization [NELAC] and are incorporated by reference into our administrative law.

NELAC is a voluntary association of State and Federal agencies with full opportunity for input from the private sector. NELAC's purpose is to establish and promote mutually acceptable performance standards for the operation of environmental laboratories. EPA's NELAP office provides support to NELAC and the evaluation of the accrediting authority programs.

NELAP oversees state and federal accrediting authorities to keep consistency between the programs. The ELCP is assessed according to

NELAC standards to be considered a NELAP accrediting authority.

As an accrediting authority the ELCP evaluates laboratories to the Utah rule which meets the requirement of the NELAC standard. This evaluation allows for any laboratory assessed under the current rule to be considered both a Utah certified laboratory and a NELAP accredited laboratory.

A laboratory that becomes NELAP accredited by another accrediting authority is eligible for Utah certification through a process of recognition. Recognition assumes the laboratory has met the NELAC standards and as such is in substantial compliance with the Utah requirements found in rule.

Proficiency Testing

With the adoption of the NELAC 2001 standards the PT requirements change slightly.

The Fields of PT move to matrix , technology, analyte.

This changes from program, analyte, and matrix. What this means to you is the PT challenges will no longer be program specific. If the same method is used for two different matrices the method will need to be challenged by both matrices. If the same technology is used for two different methods and the same matrix only one will need to be challenged.

As an example, if a laboratory holds the following Fields of Accreditation:
1. Potable Water – ICPAES/EPA 200.7 – Lead

2. Non-Potable Water – ICPAES/EPA 200.7 – Lead

3. Non-Potable Water – ICPAES/EPA 6010 – Lead

The laboratory's Fields of Proficiency Testing would be:
1. Potable Water – ICPAES – Lead

2. Non-Potable Water – ICPAES – Lead

Therefore, in the Non-Potable Water matrix, the laboratory would be required to demonstrate proficiency twice yearly by **either** of its two accredited ICPAES methods. A satisfactory result would rule the laboratory satisfactory for both methods (EPA 200.7 and EPA 6010). Similarly, an unsatisfactory result would be considered unsatisfactory for both methods.

This change is effective July 1, 2003. Each laboratory should begin to comply with the requirement for all existing fields of accreditation.

Laboratories will have until September 1, 2004 to become fully compliant with the new fields of accreditation as long as the laboratory remains compliant with all other NELAC Chapter 2 requirements.

Any PT sample analyzed after July 1, 2003 must be reported by technology/method, but laboratories may begin to analyze and report routinely scheduled PT samples by technology/method before this date.

A laboratory seeking to obtain accreditation for a new field of proficiency testing must analyze and report the PT samples by technologies/methods.

For either obtaining or maintaining accreditation, laboratories shall successfully complete two of the most recent three rounds of PT studies attempted as in the requirements of section 2.7.2.

The Environmental Testing Laboratory Certification Bulletin is published periodically by the Utah Department of Health, Division of Epidemiology and Laboratory Services, Bureau of Laboratory Improvement, to disseminate regulatory and general information to Utah certified laboratories.

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